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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,448	WEERS ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,13,14,29 and 35-47* is/are pending in the application.

4a) Of the above claim(s) *42-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 13, 14, 29, 35, 41 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/24/10 has been entered.

Claims 2-4, 6-12, 15-28 and 30-34 have been cancelled. Claims 35-47 are new. Claims 1, 5, 13, 14, 29 and 35-47 are pending and under examination.

Newly submitted claims 42-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method for the pulmonary administration of a dry powder has been examined but the new claims are directed to a composition and a kit. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5, 13, 14, 29, 35-41 and 47, drawn to methods for pulmonary administration of a dry powder from a passive dry powder inhaler and methods for inhalation, classified in class 424, subclass 489.

II. Claims 42-46, drawn to a phospholipid composition and kit, classified in class 514, subclass 75, 78.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the phospholipid powder as claimed can be used for fish food.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 5, 13, 14, 29, 35-41 and 47 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 13, 14, and 35-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as the claim recites the limitation: "a lung deposition is at least 25% over substantially the flow rate range of the inhaler" There is no support in the specification for this limitation. The limitation of: "a lung deposition is at least 25% over substantially the flow rate range of the inhaler" was not described in the specification

as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses in [0028]:

> while also providing lung deposition of at least 20%, preferably at least 25%, which is substantially independent of inhalation flow rates of <90 L/min, preferably 10-60 L/min, and most preferably 12-45 L/min.

but does not describe the instantly claimed limitation. There is no guidance in the specification to select "a lung deposition is at least 25% over substantially the flow rate range of the inhaler" and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claims 29, 38-41 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- Claim 29 introduces new matter as the claim recites the limitation: "an emitted dose is at least about 60%...an interpatient variation in lung deposition is less than about 17% and an intrapatient variation in lung deposition is less than about 6%".
- Claim 38 introduces new matter as the claim recites "wherein a difference between lung deposition at about 30 LPM and lung deposition at about 90 LPM is about 11% or less, as measured by FPF_{4+F}."

- Claim 39 introduces new matter as the claim recites "an intrasubject dose variability is about 6% or less."
- Claim 40 introduces new matter as the claim recites "where a variation in with inhalation flow rate is less than about 20%."
- Claim 41 introduces new matter as the claim recites "wherein an interpatient variation in lung deposition is less than about 17%."
- Claim 47 introduces new matter as the claim recites "inhaling the drug composition from the inhaler resulting in lung deposition wherein a variability between patients at a single flow rate is less than about 17%, and a variability with flow rate is less than about 20%."

There is no support in the specification for these limitations. The limitation of claims 29, 38-41 and 47 were not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses, for example, in Example 5 and Table 6:

was more than double TOBI (4.4 vs. 2.1 μg hr/ml). Intra-subject dose variability did not exceed 6%. The interpatient variability is summarized in Table 6.

TABLE 6

Formulation/Device	Q (LPM)	Interpatient Variability In Lung Deposition (RSD, %)
Nebulized Tobi	Tidal breathing	40
PulmoSphere Turbospin	60	17

But the specification does not describe the instantly claimed limitations. The Examiner reminds Applicant that the term 'about' provides wiggle room around the value and includes amounts greater than 6%, for example. Therefore, for example, there is no guidance in the specification to

select "an interpatient variation in lung deposition is less than about 17% and an intrapatient variation in lung deposition is less than about 6%" or any of the other limitations listed above. Applicant directed the Examiner to Example 5 and Table 6 for support in the specification for the amendments but this has been shown to be not the case. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 13, 14, 29, 35-41 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 29, 40-41 and 47 recite "less than about" and claim 46 also recites "at least about". The terms 'less than' or 'at least' provide a static value while the term 'about' provides a dynamic value. The value cannot be simultaneously static and dynamic. The Examiner suggests amending into the alternative. All dependent claims are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be examined as they read on the static value.

Claims 1, 5, 13, 14, and 35-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites: "a lung deposition is at least 25% over substantially the flow rate range of the inhaler". This is confusing as the lung deposition is a

different variable than inhaler flow rate and it is unclear how the two can be tied together. All dependent claims are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be examined as they read on lung deposition is at least 25%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 13, 14, 29, 35-41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. (US 5934273) and Eljamal et al. (WO 96/32096: reference BH on the IDS filed on 5/5/03) and Hanes et al. (US 5,855,913) and Radhakrishnan (US 5,049389) as evidenced by Swarbrick et al. (Encyclopedia of Pharmaceutical Technology 1994, vol 9, pages 288-290).

Applicant claims a method for the pulmonary administration of a dry powder composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Andersson et al. teach methods of dispensing a dose of a pharmaceutically active compound comprising providing ***a dry powder inhaler*** containing a powder comprising the pharmaceutically active compound that is stored in the inhaler and consists of particles having a diameter of *less than about 10 microns*; administering the dose to the patient via inhalation through the inhaler with an emitted dose *of at least 40%* which means values greater than 40% including at least 60% or at least 80% are taught (Claim 1). The type of inhaler used is TURBUHALER (column 1, lines 17-19, 66; column 3, line 44; figure 1; and examples 1-5). The Examiner notes that ***Applicant also teaches TURBUHALER as the dry powder inhaler on page 21 Table 2, for example***. There are no motor, rotating or vibrating parts to the TURBUHALER, which makes it a *passive dry powder inhaler* **as evidenced by Swarbrick et al.** who teach different dry powder inhalers such as the ROTAHALER and TURBUHALER and establish their equivalence (Figures 1 and Figure 2, pages 288-289). ***In addition, Andersson et al. teach breath activation of the inhaler device (claim 2) thus making it a passive device***. Furthermore, it is the Examiner's position that since it is the same dry powder inhaler as used by Applicant then it intrinsically has the same resistance as instantly claimed. The target peak inhalation flow rate for the TURBUHALER was 60 l/min (column 6, line 60). The geometric mean of budesonide deposited and absorbed in the lung was 32% with the range of 16%-**59% and 59%** is greater than the instantly claimed amounts of greater than 25%, 30%, and 50% (column 6, lines 35-37,

for example). Andersson et al. teach that *any pharmaceutical active* compound, including antibiotics, can be formulated into a powder with *appropriate powder characteristics* (column 4, lines 1-35). The pharmaceutically active compound can be contained in a pharmaceutical formulation containing common additives such as diluents and carrier substances (column 3, lines 48-67). Thus, Andersson et al. provide an inhaler device and teach placing essentially any active with any powder characteristics in it.

Eljamal et al. teach compositions for dry powder inhalers and methods of treating conditions by oral inhalation with particles that have a mass mediam aerodynamic diameter of less than 5 microns (page 20, line 24; Page 35, Table 2; page 37, Table 3; and claims 1-33). Eljamal et al. teach that particles of less than 5 micron size can be delivered to the deep lung for systemic circulation (page 20, lines 10-14).

Hanes et al. teach aerodynamically light particles incorporating a surfactant for drug delivery to the pulmonary system that has a tap density of less than about 0.4 g/cm^3 (Abstract; column 9, lines 1-55; and claims 1-33). Hanes et al. teach that the "mass mean diameter of the particles can be measured using a Coulter Multisizer II (Coulter Electronics, Luton, Beds, England). The aerodynamically light particles in one preferred embodiment are at least about 5 microns in diameter." (column 7, lines 54-58). It is the Examiner's position that "at least about 5 microns" includes values less than 5 microns as well as values at least 5 microns. Hanes et al. teach phospholipids as the surfactant in claims 14-17:

14. The composition of claim 1 wherein the surfactant is selected from the group consisting of a fatty acid, a phospholipid, and a poloxamer.

15. The composition of claim 1 wherein the surfactant is a phosphoglyceride.

16. The composition of claim 1 wherein the surfactant is dipalmitoyl L-α-phosphatidylcholine.

Hanes et al. teach any surfactant known in the art can work in column 5, lines 39-47:

Surfactants known in the art can be used including any naturally occurring lung surfactant. Other exemplary surfactants include diphosphatidyl glycerol (DPPG); hexadecanol; fatty alcohols such as polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid, such as palmitic acid or oleic acid; sorbitan trioleate (Span 85); glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester such as sorbitan trioleate; tyloxapol and a phospholipid.

Hanes et al. teach porous microparticles (column 16, lines 25-35, for example) and since the microparticles are porous they contain spaces within and are thus also hollow in the absence of evidence to the contray.

Hanes et al. teach a wide variety of therapeutic agents including parathyroid hormone and leuprolide (column 10, lines 37-49 and claim 25).

Radhakrishnan teach inhalation method for treatment of lung diseases with tobramycin and other actives (claims 13, 15, 18 and 20).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach the mass median aerodynamic diameter of less than 5 microns and the bulk density of less than 0.5 g/cm3 or the specific lung deposition related to flow rate. This deficiency in Andersson et al. is cured by the teachings Eljamal et al. and Hanes et al.

2. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach a lipid matrix that comprises phospholipids or hollow porous microparticles; or the interpatient and intrapatient variations. This deficiency in Andersson et al. is cured by the teachings of Hanes et al. and common sense.

3. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach an active agent selected from the group consisting of tobramycin sulfate, leuprolide acetate, amphotericin B, ciprofloxacin and parathyroid hormone. This deficiency in Andersson et al. is cured by the teachings of Hanes et al. and Radhakrishnan.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use mass median aerodynamic diameter of less than 5 microns and the bulk density of less than 0.5 g/cm^3 in the method of Andersson et al., as suggested by Eljamal et al. and Hanes et al., and obtain the proper lung deposition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Andersson et al. suggest using any powder characteristics and: a) Eljamal et al. teach the beneficial property of obtaining deep lung delivery for systemic circulation with particles less

than 5 micron in size; and b) Hanes et al. provide some guidelines on the diameter and density of the particles for one of ordinary skill in the art; and 2) the particles used by Andersson et al. must possess a diameter and density and the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics such as diameter and density. Andersson et al. teach an unagglomerated particle size of less than about 10 microns in diameter (claim 1 (c)) which would read on particles of less than 5 microns. Andersson et al. simply did not calculate the mass median aerodynamic diameter or measure the bulk density. The burden is properly shifted to applicant to show otherwise. The lung deposition is within what is claimed by Applicant.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use hollow porous phospholipid, such as dipalmatoylphosphatidylcholine, inert lipid matrix carriers in the method of Andersson et al., as suggested by Hanes et al., and provide the instant the interpatient and intrapatient variations and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: Andersson et al. suggests using common pharmaceutical formulation containing additives/carriers and Hanes et al. provide the nexus teaching to use phospholipids in dry powder inhalation pharmaceutical compositions. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Thus the disclosure of Hanes would render

obvious the other species of instant claim 5 in the absence of evidence to the contrary. Hanes teaches that porosity affects the tap density which in turn regulates the aerodynamics and increasing porosity permits delivery of larger particle envelope volumes into the lungs (column 9, lines 2-12 and 19-25 and general discussions in this column), which is a desirable feature with inhaled medications. Furthermore, with regard to the inter- and intrapatient limitations, it is the Examiner's position that this would be intrinsic because "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). *In other words, reduced variability in the lung dose is an intrinsic feature.*

With regard to the Anderson Cascade Impaction or multi-stage liquid impinger limitations, please note that the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics such as diameter and density. The burden is properly shifted to applicant to show otherwise.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select actives from the group consisting of tobramycin sulfate, leuprolide acetate, amphotericin B and parathyroid hormone in the method of Andersson et al., as suggested by Hanes et al. and Radhakrishnan, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Andersson et al. teach using any pharmaceutical active. The selection of the sulfate salt of tobramycin is merely a matter of judicious selection by one of ordinary skill in the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments:

Applicant asserts that Andersson does not teach a lung deposition of particles to the deep lung of more than 25% as claimed and that Andersson does not teach or suggest a FPF measurement and that the Andersson is devoid of any teaching of any lipid. Applicant asserts that the other references to not make up for the deficiencies of Andersson and there is no basis in either reference for combining it with any of the others. Respectfully, the Examiner cannot agree for the following reasons. Andersson teaches a particle size of less than 10 microns for optimal deposition in the lung (column 2, lines 8-10 and 19-26). Since the particle size is the same as claimed then the particles intrinsically reach the deep lung and the amount deposited has been previously discussed. Andersson may not discuss a FPF measurement but that is irrelevant as such a measurement can be performed by the ordinary artisan. Andersson may not discuss lipids

but suggests commonly used additives and diluents and/or carrier substances (column 3, lines 48-53 and 58-60) which is why the secondary references have been joined.

Applicant's assertion that the secondary references do not teach a passive dry powder inhaler is without merit as the primary reference teaches a passive dry powder inhaler and the other references substantiate the Examiner's position especially when Applicant is also teaching use of the TURBUHALER as discussed above.

Applicant argues that claim 29 is patentable over the combined references. It is the Examiner's position that it is not patentable as discussed above.

Respectfully, Applicant's arguments are not persuasive and nothing unexpected or surprising has been shown. The expected result is a method of pulmonary administration of a dry powder. ***The Examiner can determine no patentable subject matter.***

The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 5, 13, 14, 29, 35-41 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, 22 and 36-38 of copending Application No. 10/141,219 (now revived) in view of Andersson et al. (US 5934273) Hanes et al. (US 5,855,913). The copending application teaches methods for administering a dry powder composition comprised of leupolide and phospholipid with a median diameter of between 0.5-4 microns, aerodynamic diameter of less than 5 microns, bulk density of about 0.5 g/cm3, dry powder inhaler, emitted dosages, and various phospholipids.

The copending application does not expressly disclose the resistance of the passive dry powder inhaler or hollow porous particles. This deficiency is cured by the teachings of Andersson et al. and Hanes et al., which are discussed in detail above and those discussions are hereby incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application and Andersson et al. and Hanes et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

2. Claims 1, 5, 13, 14, 29, 35-41 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-25, 29 and 30 of copending Application No. 11/187,757 in view of Andersson et al. (US 5934273) Hanes et al. (US 5,855,913). The copending application is drawn to methods for treating a patient

comprising administering particulates via inhalation having a mass median diameter of less than 20 microns, lipid matrix, amphotericin B, and a geometric diameter of less than 3 microns.

The copending application does not expressly disclose the resistance of the dry powder inhaler or hollow porous particles. This deficiency is cured by the teachings of Andersson et al. and Hanes et al., which are discussed in detail above and those discussions are hereby incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application and Andersson et al. and Hanes et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

This is a provisional obviousness-type double patenting rejection.

Claims 1, 5, 13, 14, 29, 35-41 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-15, 17-19, 21-24, 26-34, 36-38, and 39-57 of U.S. Patent No. 7,306,787 in view of Andersson et al. (US 5934273). The patented claims are drawn to a method of delivering a therapeutic dose of a bioactive agent to the pulmonary air passages with a bulk density of less than 0.5 g/cm^3, porous particles, diameter of 1-30 microns, emitted particles of at least 50% are delivered and an aerodynamic diameter of less than 5 microns. Phospholipids and actives as instantly claimed are taught.

The US Patent does not expressly disclose the resistance of the dry powder inhaler. This deficiency is cured by the teachings of Andersson et al. which are discussed in detail above and those discussions are hereby incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance.

One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patented claims and Andersson et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

Response to arguments:

Applicant will address the double patenting rejections upon the indication of allowable subject matter. Until that time the claims remain rejected.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Primary Examiner, Art Unit 1616